UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

FEB 5 2001

David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 5,886,036, was filed on November 10, 2000, under 35 U.S. C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, lopinavir, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use. Lopinavir is said to have been approved for commercial use or sale with another active ingredient, ritonavir, in the product having the tradename KALETRA. The assistance of your Office is also requested in confirming that the application for patent term extension was filed within sixty days after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

cc: Steven F. Weinstock
ABBOTT LABORATORIES
D377/AP6D-2
100 ABBOTT PARK ROAD
ABBOTT PARK, IL 60064-6050